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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/589,535 | 08/16/2006 | Klaus Abraham-Fuchs | 32860-01079/US | 8477 |

30596 7590 10/27/2009
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| EXAMINER |
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PATEL, NEHA

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| ART UNIT | PAPER NUMBER |
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3686

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| MAIL DATE | DELIVERY MODE |
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10/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/589,535 | Applicant(s) ABRAHAM-FUCHS ET AL. | |
| | Examiner NEHA PATEL | Art Unit 3686 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This is first office action on the merits in response communication filed on 08/16/2006.
2. Claims 1-17 are currently pending and have been examined.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 08/16/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 has a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of

ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claimed process is eligible for patent protection under 35 U.S.C. § 101 if: "(1) It is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that

does not include particular machines.');

Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing' '); Cochrane v. Deener, 94 U.S. 780, 788 (1876) ('A process is...an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').⁷ A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article." (In re Bilski, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008)).

Also noted in Bilski is the statement, "Process claim that recites fundamental principle, and that otherwise fails 'machine-or-transformation' test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if

recited machine or transformation constitutes mere 'insignificant post-solution activity.'" (In re Bilski, 88 USPQ2d 1385, 1385 (Fed. Cir. 2008)) Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test. It is also noted that the mere recitation of a machine in the preamble in a manner such that the machine fails to patentably limit the scope of the claim does not make the claim statutory under 35 U.S.C. § 101, as seen in the Board of Patent Appeals Informative Opinion Ex parte Langemyr et al, (Appeal 2008-1495).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 5, 7-9, 13, 15, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (**US 2002/0154010 A1**).

With respect to claim 1:

Tu et al. teaches *a method for a clinical study, in which an occurrence of an event during the study elicits collaboration between responsible study personnel*,
Tu et al. teaches the method comprising:

- *receiving the event at a collaboration system; (By disclosing, Upon **detection of various events and/or conditions with respect to the events**, the present invention enables a notification message to be sent in accordance with a set of notification preferences. See at least paragraph [0018].)*
- *identifying, via the collaboration system and on the basis of parameters assigned to the event, a group of responsible study personnel needed for the collaboration; (By disclosing, notification may be provided to the **appropriate entities** in a manner suitable for the situation prompting the notification. See at least paragraph [0018].)*
- *providing, via the collaboration system, a communications platform for the group to undertake the collaboration; (By disclosing message bus in fig. 1. See at least fig. 1 as well as associated text.)*
- *checking, via the collaboration system, the collaboration on the basis of verification criteria. (By disclosing, the persist flag may be **checked to verify** that the event is to be discarded in association with the follow-by paired event condition. See at least paragraph [0124].)*

With respect to claim 17:

System claim 17 repeat the subject matter of method claim 1, as a set of apparatus elements rather than a series of steps. As the underlying processes of claim 1 have been shown to be fully disclosed by the teachings of [Tu et al.] in the above rejections of claim 1, it is readily apparent that the system disclosed by [Tu et al.]

includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 1 and incorporated herein.

With respect to claim 2:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system, as a communications platform, provides a central information bus and provides each responsible study personnel member of the group with an information channel to the information bus.* (By disclosing message bus in fig. 1. See at least fig. 1 as well as associated text.)

With respect to claims 4 and 13:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system, using the parameters assigned to the event, establishes a content or time framework for the collaboration and communicates this to the group.* (See at least paragraph [0022].)

With respect to claim 5:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system uses at least one of content and time framework as a verification criterion and, when the collaboration is over, checks compliance with the verification criteria.* (By disclosing, In addition, timing flows (e.g., fired timer events) are further indicated by dotted lines. Thus, in this example, if the second following event is never received, or not received within the specified time, the stored event data for the entering event (i.e., first event) is located at block 2642 and discarded at block 2644. More

particularly, the persist flag may be checked to verify that the event is to be discarded in association with the follow-by paired event condition. See at least paragraph [0124].)

With respect to claims 7 and 15:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is a prompt for collaboration which is defined within the framework of the study.* (See at least paragraph [0113].)

With respect to claims 8 and 16:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is an unforeseeable event arising during the study.* (See at least paragraph [0066].)

With respect to claim 9:

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is found by a monitoring system combing through the study database data for anything striking.* (See at least paragraph [0022].)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (**US 2002/0154010 A1**) in view of Wagner (**US 6,092102 A**).

With respect to claims 3 and 12:

Tu et al. teaches limitations shown above. Tu et al. does not specifically disclose *the collaboration system, ascertains, using the parameters assigned to the event, available data needed for collaboration that are in at least one of a database containing medical knowledge and study database, extracts the data from the database, and*

makes the data available to the group on the communications platform. However Wagner teaches the collaboration system, ascertains, using the parameters assigned to the event, available data needed for collaboration that are in at least one of a database containing medical knowledge and study database, extracts the data from the database, and makes the data available to the group on the communications platform. (see at least fig. 1 as well as associated text.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of collaboration disclosed by Tu et al. with the technique of extracts the data from the database, and makes the data available to the group on the communications platform disclosed by Wagner to improve the quality and lower the cost of health care by providing information to health care providers as they need it. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

With respect to claim 14:

Tu et al. teaches limitations shown above in view of Wagner. Tu et al. further teaches *the collaboration system, using the parameters assigned to the event, establishes a content or time framework for the collaboration and communicates this to the group. (See at least paragraph [0022].)*

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. **(US 2002/0154010 A1)** in view of Schmidt et al. **(US 6,839,678 B1)**.

With respect to claim 6:

Tu et al. teaches limitations shown above. Tu et al. does not specifically disclose *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member*. However Schmidt et al. teaches *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member*. (See at least column 5, 1st paragraph.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of collaboration disclosed by Tu et al. with the technique of having *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member* disclosed by Schmidt et al. so no eligible person left out of study. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

15. Claims 10 and 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. **(US 2002/0154010 A1)** in view of Official Notice taken by examiner.

With respect to claims 10 and 11:

Tu et al. teaches limitations shown above. Tu et al. does not specifically disclose *the collaboration is documented and the collaboration is archived*. However examiner

takes official notice that it is old and well known to document and archived collaboration so study personnel's opinion and result of study can be useful for future studies which make less work in upcoming studies.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Neha Patel** whose telephone number is **571.270.1492**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY, O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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/N. P./

Examiner, Art Unit 3686

October 23, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686